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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/364,967 07/31/99 KELLY

K P-8035

EXAMINER

MM91/1003

MEDTRONIC INC
7000 CENTRAL AVENUE N E
MINNEAPOLIS MN 55432

TSAT, C

ART UNIT

PAPER NUMBER

2857

DATE MAILED:

10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/364,967

Applicant(s)

KELLY ET AL.

Examiner

Carol S Tsai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18, 19 and 21-39 is/are rejected.
- 7) ☒ Claim(s) 17, 20, 28 and 30-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

At page 13, line 6, "telemetry 38" is not clear to understand because reference number 38 is defined as alarm and there are two different term of telemetry being defined in page 3, lines 19 and 20, IPG telemetry system 14 and programmer telemetry system 16.

Claim Objections

2. Claims 28 and 30-34 are objected to because of the following informalities:

In claim 28 line 2, "a alarm" should read - - an alarm - -.

In claim 30 line 3, "the a voltage" should read - - the voltage - -.

Appropriate correction is required.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

"2" at page 3, lines 9.

Correction is required.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "36" has been used to designate both direct connection and display screen.
Correction is required.

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5. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-16, 18, 19, 21-24, 29, 30-34, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by U. S. Patent No. 5,344,431 to Merritt et al.

With respect to claims 1, and 29, Merritt et al. disclose a method of determining the current status and remaining life of a power source in an implantable neurological tissue stimulator comprising the steps of assessing the power source voltage of the power source in an implantable neurological tissue stimulator (see Abstract, lines 1-10; col. 2, lines 24-44; and col. 3, lines 42-55) ; determining, based on the assessed power source voltage, where the power source is in its power source life cycle (see col. 9, lines 50-56); and taking appropriate action in response to the determination of where the power source is in its power source life cycle (see col. 9, lines 63 to col. 10, line 2).

As to claim 2, Merritt et al. also disclose the power source voltage being done by connecting the power source to an analog to digital (A/D) converter (A/D converter 108 shown on Fig. 6 and see col. 6, lines 42-47).

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As to claims 3 and 4, Merritt et al. also disclose determining the remaining power source capacity/the remaining life time of the power source (see col. 2, lines 37-40 and col. 9, lines 50-57).

As to claim 5-8, Merritt et al. also disclose determining the probable usage rate of the power source and dividing the determined remaining capacity by the probable usage rate of the power source (see col. 9, line 50 to col. 10, lines 2).

As to claims 9-10, Merritt et al. also disclose determining the used capacity of the power source since the last time the implantable neurological tissue stimulator was reprogrammed (see col. 9, lines 67 to col. 10, line 2).

As to claim 11, Merritt et al. also disclose determining the used power source capacity (see col. 9, line 67 to col. 10, line 2).

As to claims 12, 13, 31, and 32, Merritt et al. do not disclose expressly correlating, in a “look-up table”, the power source voltage assessed in the step of assessing the power source voltage to a predetermined “power source capacity remaining”/ “power source capacity used” value.

It is, however, considered inherent that Merritt et al. correlating, in a “look-up table”, the power source voltage assessed in the step of assessing the power source voltage to a predetermined “power source capacity remaining”/ “power source capacity used” value (see col. 9, lines 63-67), because such correlating is known to be a necessary step in order to make a determination of battery end-of-service in a medical device.

As to claims 14 and 15, Merritt et al. do not disclose expressly determining the power source capacity used/remaining and then subtracting this value from the total source capacity in where the power source capacity remaining is determined.

It is, however, considered inherent that Merritt et al. determining the power source capacity used/remaining and then subtracting this value from the total source capacity in where the power source capacity remaining is determined (see col. 9, line 67 to col. 10, line 2), because such determining is known to be an necessary step in order to calculate the power source capacity used/remaining in a medical device.

As to claims 16, 18, 19, 21, 33, and 34, Merritt et al. also disclose calculating the remaining power source capacity/power source capacity used by using a non-linear formula (see col. 9, lines 53-62).

As to claim 22, Merritt et al. also disclose informing the user of where in the power source life the power source is (see col. 9, line 66 to col. 10, line 2).

As to claims 23 and 24, Merritt et al. also disclose displaying a representation of the percentage of power source capacity used/remaining (see col. 7, lines 42-46).

As to claim 35, Merritt et al. also disclose the power source being a battery (see col. 6, lines 39-47).

As to claim 30, Merritt et al. also disclose a device for determining the current status and determining life of a power source in an implantable neurological tissue stimulator, the implantable neurological tissue stimulator having: a source of power (see Abstract, lines 1-10; col. 2, lines 24-44; and col. 3, lines 42-55); a voltage determining system for determining the voltage of the source of power (see col. 9, lines 50-56); a programmer (programmer 20 shown on

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Fig. 3) for creating and processing information to be sent to and received from the implantable neurological tissue stimulator, the programmer including a process and a memory (memory 104 shown on Fig. 6) attached; a system for communicating information between the implantable neurological tissue stimulator and the programmer in which the voltage determining system for determining the voltage of the source of power passed the determined voltage of the source of power to the system for communication; and in which the system for communication passes the determined voltage of the source of power from the implantable neurological tissue stimulator to the programmer and to the processor (microprocessor 104 shown on Fig. 6), and in which the processor determines, based on the determined voltage of the source of power, where the source of power is in its life cycle and takes appropriate action in response to the determination of where the source of power is in its life cycle (see col. 3, lines 42-54; col. 6, lines 28-38; col. 9, lines 63 to col. 10, line 2).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merritt et al. in view of U. S. Patent No. 5,994,876 to Canny et al.

As noted above, with respect to claims 25-27, Merritt et al. disclose the claimed invention, expect for determining whether the remaining power source capacity falls within a

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predetermined limit; alerting the user if the remaining power source capacity falls within a predetermined limit; and alerting the user by trigger an alarm.

Canny et al. teach determining whether the remaining power source capacity falls within a predetermined limit (see col. 8, lines 20-26); alerting the user if the remaining power source capacity falls within a predetermined limit; and alerting the user by trigger an alarm (see col. 8, lines 26-28).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Merritt et al.'s method to include steps of determining whether the remaining power source capacity falls within a predetermined limit; alerting the user if the remaining power source capacity falls within a predetermined limit; and alerting the user by trigger an alarm, as taught by Canny et al., in order to recharge the battery (Canny et al. col. 8, line 28).

As to claim 28, Merritt et al. do not disclose triggering an alarm chosen from the group consisting of audible or visual warnings.

Canny et al. teach triggering an alarm chosen from the group consisting of audible or visual warnings (see col. 8, lines 25-28).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Merritt et al.'s method to include triggering an alarm chosen from the group consisting of audible or visual warnings, as taught by Canny et al., in order to recharge the battery (Canny et al. col. 8, line 28).

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10. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Merritt et al. in view of U. S. Patent No. 6,099,495 to Kinghorn et al.

As noted above, Merritt et al. disclose the claimed invention, except for the power source being a capacitor.

Kinghorn et al. teach the power source being a capacitor (see Abstract, lines 1-4; col. 1, lines 65 to col. 2, line 2; and col. 2, lines 61 to col. 3, line 2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Merritt et al.'s method to include the power source being a capacitor, as taught by Kinghorn et al., in order to power an implantable electrical transducer capable of moving from one position to another for providing treatment for the patient (Kinghorn et al. col. 1, line 67 to col. 2, lines 2).

11. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merritt et al. over U. S. Patent No. 5,807,397 to Barreras.

With respect to claims 37 and 38, Merritt et al. disclose implanting in the patient a pulse generator (pulse generator 10 shown on Fig. 3) having a power source, and a lead (cardiac pacing lead 12 shown on Fig. 3) connected to the pulse generator and stimulating nervous tissue with electrical pulses generated by the pulse generator and communicated by the lead (see col. 4, lines 38-44) and determining the status and remaining life of the power source (see col. 3, lines 42-54; col. 6, lines 28-38; col. 9, lines 63 to col. 10, line 2).

Merritt et al. do not disclose controlling the pulse generator within preset limits by patient to adjust stimulation of nervous tissue.

Barreras teaches controlling the pulse generator within preset limits by patient to adjust stimulation of nervous tissue (see col. 18, lines 31-46 and col. 19, lines 18-23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Merritt et al.'s method to include controlling the pulse generator within preset limits by patient to adjust stimulation of nervous tissue, as taught by Barreras, in order to control the stimulation current pulse.

12. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Merritt et al. in view of Canny et al. as applied to claims 1, 22, 25, 26, and 27 above, and further in view of U. S. Patent No. 5,807,397 to Barreras.

As to claim 39, Merritt et al. disclose implanting in the patient a pulse generator (pulse generator 10 shown on Fig. 3) having a power source, and a lead (cardiac pacing lead 12 shown on Fig. 3) connected to the pulse generator and stimulating nervous tissue with electrical pulses generated by the pulse generator and communicated by the lead (see col. 4, lines 38-44) and determining the status and remaining life of the power source (see col. 3, lines 42-54; col. 6, lines 28-38; col. 9, lines 63 to col. 10, line 2)

Merritt et al. in combination with Canny et al. do not disclose controlling the pulse generator within preset limits by patient to adjust stimulation of nervous tissue.

Barreras teaches controlling the pulse generator within preset limits by patient to adjust stimulation of nervous tissue (see col. 18, lines 31-46 and col. 19, lines 18-23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Merritt et al. in combination of Canny et al.'s method to include

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controlling the pulse generator within preset limits by patient to adjust stimulation of nervous tissue, as taught by Barreras, in order to control the stimulation current pulse.

Allowable Subject Matter

13. Claims 17 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Canny et al. disclose an electronic circuit and a method for accurately measuring intermittent current pulses supplied by a storage battery to energize a load.

Duggan discloses an improved telemetry transmission system for transmitting electrocardiographic information, indications of the occurrence of the pacing pulse and for transmitting digitally encoded information from an implanted pacemaker, an implanted drug dispensing device, or other implanted device, to a remote receiver.

Fischell et al. disclose a system for detecting a myocardial infarction (i.e., a heart attack) at the earliest possible time and promptly warning the patient that he should immediately seek medical care.

Prutchi et al. disclose an implantable medical device for electrically stimulating the heart

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to beat generally includes a processor, a plurality of electrodes, a sense amplifier, a pulse generator, and a heart status monitor.

Fischell et al. disclose a completely implantable system that can detect the occurrence of a myocardial infarction, i.e., a heart attack, and automatically inject a thrombolytic and/or anti-thrombogenic agent into the bloodstream to promptly dissolve the thrombus that caused the myocardial infarction and prevent the formation of additional thrombi.

Davis et al. disclose a cardiac stimulation device having a reduced volumetric configuration contains a pair of high-voltage cylindrical discharge capacitors positioned at rounded edges within a device container.

Munshi et al. disclose an improved hermetically-sealed automatic implantable cardioverter-defibrillator (AICD) or any other bioimplantable device which may be operated on a single rechargeable cell, or a dual power source system, the rechargeable component being recharged by magnetic induction.

Kopmann discloses a method of and an apparatus for monitoring the state of charge of a rechargeable battery are disclosed which use a reference value corresponding to a defined state of charge stored in a memory.

Langer discloses a fully implantable defibrillator in which the components of the defined within the implantable casing are two chambers.

Contact Information

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carol S. Tsai whose telephone number is (703) 305-0851. The


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examiner can normally be reached on Monday-Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on (703) 308-1677. The fax number for TC 2800 is (703) 305-7382. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC 2800 receptionist whose telephone number is (703) 308-1782.

In order to reduce pendency and avoid potential delays, Group 2800 is encouraging FAXing of responses to Office actions directly into the Group at (703) 308-7382. This practice may be used for filing papers not requiring a fee. It may also be used for filing papers which require a fee by applicants who authorize charges to a PTO deposit account. Please identify the examiner and art unit at the top of your cover sheet. Papers submitted via FAX into Group 2800 will be promptly forwarded to the examiner.

Carol S. Tsai

09/22/01


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